DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 203 and 205

[Docket No. 92N–0297]

RIN 0905–AC81

DMB

Display Date 2-12-02
Publication Date 2-13-02
Certifier R. LEDESMA

Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures; Delay of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; delay of effective date.

SUMMARY: The Food and Drug Administration (FDA) is further delaying, until April 1, 2003, the effective date of certain requirements of a final rule published in the **Federal Register** of December **3,** 1999 **(64** FR **67720).** In the **Federal Register** of May 3, 2000 (65 FR 25639), the agency delayed until October 1, 2001, the effective date of certain requirements in the final rule relating to wholesale distribution of prescription drugs by distributors that are not authorized distributors of record, and distribution of blood derivatives by entities that meet the definition of a "health care entity" in the final rule. In **the Federal Register** of March 1, 2001 (66 FR 12850), the agency further delayed the effective date of those requirements until April 1, 2002. This action further delays the effective date of these requirements until April 1, 2003. The final rule implements the Prescription Drug Marketing Act of 1987 (PDMA), as modified by the Prescription Drug Amendments of 1992 (PDA), and the Food and Drug Administration Modernization Act of 1997 (the Modernization Act). The agency is taking this action to address concerns about the requirements raised by affected parties. As explained in the **SUPPLEMENTARY INFORMATION** section, the delay will allow additional time for Congress and FDA to consider whether legislative and regulatory changes are appropriate.

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To the extent that 5 U.S.C. 553 applies to this action, it is exempt from notice and comment because it constitutes a rule of procedure under 5 U.S.C. 553(b)(A). Alternatively, the agency's implementation of this action without opportunity for public comment, effective immediately upon publication today in the **Federal Register,** is based on the good cause exceptions in 5 U.S.C. 553(b)(B) and (d)(3). Seeking public comment'is impracticable, unnecessary, and contrary to the public interest. As explained in the **SUPPLEMENTARY INFORMATION** section, FDA has prepared a report for Congress and concluded that although the agency can address some of industry's concerns with the PDMA regulation through regulatory changes, other concerns would have to be addressed by Congress through legislative action. The further delay is necessary to give Congress time to consider the information and conclusions contained in the agency's report, and to determine if legislative action is appropriate. The further delay will also give the agency additional time to consider whether regulatory changes are appropriate and, if so, to initiate such changes.

DATES: The effective date for §§ 203.3(u) and 203.50, and the applicability of § 203.3(q) to wholesale distribution of blood derivatives by health care entities, added at 64 FR 67720, December 3, 1999, is delayed until April 1, 2003. Submit written or electronic comments by [*insert date 60 days after date of publication in the* **Federal Register].**

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document. Submit electronic comments on the Internet at http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Lee D. Korb, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

SUPPLEMENTARY INFORMATION: PDMA (Public Law 100-293) was enacted on April 22, 1988, and was modified by the PDA (Public Law 102–353, 106 Stat. 941) on August 26, 1992. The PDMA, as modified by the PDA, amended sections 301, 303, 503, and 801 of the Federal Food,

Drug, and Cosmetic Act (the act) (21 U.S.C. 331, 333, 353, 381) to, among other things, establish requirements for the wholesale distribution of prescription drugs and for the distribution of blood derived prescription drug products by health care entities.

On December 3, 1999, the agency published final regulations in part 203 (21 CFR part 203) implementing PDMA (64 FR 67720). After publication of the final rule, the agency received letters and petitions and had other communications with industry, industry trade associations, and members of Congress objecting to the provisions in §§ 203.3(u) and 203.50. On March 29, 2000, the agency met with representatives from the wholesale drug industry and industry associations to discuss their concerns. In addition, FDA received a petition for stay of action requesting that the relevant provisions of the final rule be stayed until October 1, 2001. The agency also received a petition for reconsideration from the Small Business, Administration requesting that FDA reconsider the final rule and suspend its effective date based on the severe economic impact it would have on more than 4,000 small businesses.

In addition to the submissions on wholesale distribution by unauthorized distributors, the agency received several letters on, and held several meetings to discuss, the implications of the final regulations for blood centers that distribute blood derivative products and provide health care as a service to the hospitals and patients they serve.

Based on the concerns expressed by industry, industry associations, and Congress about implementing §§ 203.3(u) and 203.50 by the December 4, 2000, effective date, the agency published a document in the **Federal Register** of May 3, 2000 (65 FR 25639), delaying the effective date for those provisions until October 1, 2001. In addition, the May 2000 action delayed the applicability of § 203.3(q) to wholesale distribution of blood derivatives by health care entities until October 1, 2001. The May 2000 action also reopened the administrative record and gave interested persons until July 3, 2000, to submit written comments. As stated in the May 2000 action, the purpose of delaying the effective date for these provisions was to give the agency

time to obtain more information about the possible consequences of implementing them and to further evaluate the issues involved.

On May 16, 2000, the House Committee on Appropriations (the Committee) stated in its report accompanying the Agriculture, Rural Development, IDA, and Related Agencies Appropriations Bill, 2001 (H. Rept. 106-619) that it supported the "recent FDA action to delay the effective date for implementing certain requirements of the Prescription Drug Marketing Act until October 1, 2001, and reopen the administrative record in order to receive additional comments." In addition, the Committee stated that it "believes the agency should thoroughly review the potential impact of the proposed provisions on the secondary wholesale pharmaceutical industry." The Committee directed the agency to provide a report to the Committee summarizing the comments and issues raised and agency plans to address the concerns.

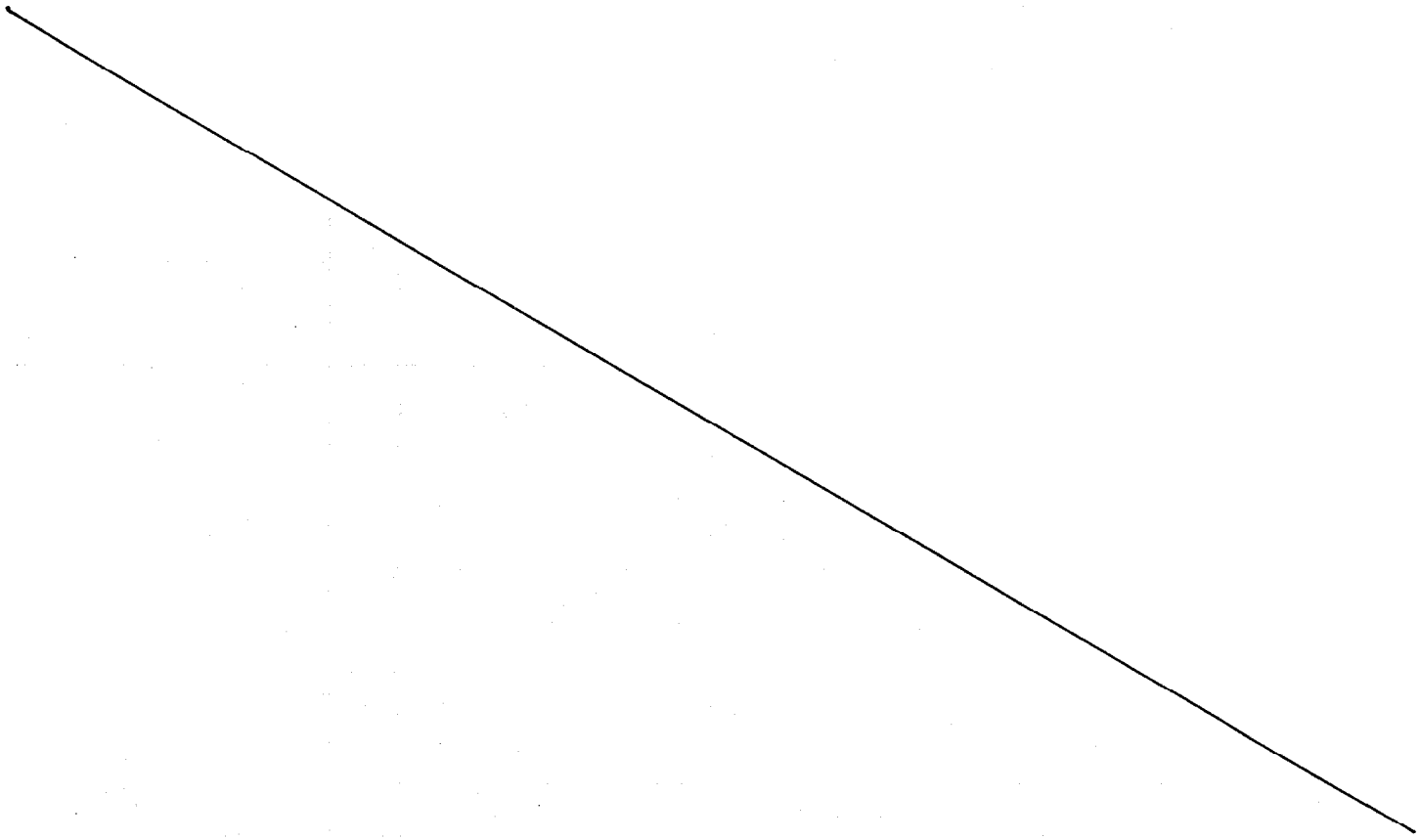
After issuing the delay of the effective date for the relevant requirements of the final rule, the agency decided to hold a public hearing to elicit comment from interested persons on the requirements. In the **Federal Register** of September 19, 2000 (65 FR 56480), the agency announced that a public hearing would be held on October 27, 2000, to discuss the requirements at issue (i.e., the requirements for unauthorized distributors and the provisions relating to distribution of blood derivatives by health care entities). The hearing was held on October 27, 2000, and comments were accepted until November 20, 2000.

In the **Federal Register** of March 1, 2001 (66 FR 12850), the agency announced that it was further delaying, until April 1, 2002, the effective date of the provisions relating to wholesale distribution of prescription drugs by unauthorized distributors (i.e., §§ 203.3(u) and 203.50). The agency also further delayed the applicability of § 203.3(q) to wholesale distribution of blood derivatives by health care entities. As explained by the agency, the effective date was further delayed to give FDA additional time to consider comments and testimony received on unauthorized distributor and blood, derivative issues, for FDA to prepare its report to Congress, and, if

appropriate, for Congress or the agency to make legislative or regulatory changes. The report was completed and submitted to Congress on June 7, 2001.

In its report to Congress, the agency concluded that it could address some, but not all, of the concerns raised by the secondary wholesale industry and the blood industry through regulatory changes. However, Congress would have to act to amend section 503(e) of the act to make the types of changes requested by the secondary wholesale industry.

FDA has decided that, in light of the fact that only legislative action can address some of the concerns raised by the secondary wholesale industry, it is appropriate to further delay the effective date of the relevant provisions of the final rule for another year until April 1, 2003. The delay will give Congress time to consider the information and conclusions contained in the agency's report and to determine if legislative action is appropriate. The further delay will also give the agency additional time to consider whether regulatory changes are appropriate and, if so, to initiate such changes.



This action is being taken under FDA's authority under 21 CFR 10.35(a). The Commissioner of Food and Drugs finds that this further delay of the effective date is in the public interest.

Dated: 2/5/2

February 5; 2002.

Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 02–????? Filed ??–??–02; 8:45 am]

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